UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Case No.: 1:17-CR-00027**
	)	
JOEL A. SMITHERS	)	

MOTION IN LIMINE TO EXCLUDE AND/OR LIMIT JOEL A. SMITHERS' PROPOSED EXPERT TESTIMONY

Pursuant to Federal Rules of Evidence 402, 403, 702, 703, and 704, and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) and its progeny, and for the reasons set forth herein, the United States of America, by counsel, respectfully moves to exclude the testimony of Joel A. Smithers' proposed expert—James Patrick Murphy, M.D.—at trial as the proposed testimony is not based on sufficient facts or data, is not the result of reliable principles or methods, does not reflect a reliable application of the methods and principles to the facts of this case, and would otherwise confuse the issues and mislead the jury. In the alternative, the Government respectfully moves to limit Dr. Murphy's proposed testimony to only those issues that the Court determines he is qualified to opine and are relevant.[1]

[1] Smithers failed to file his list of witnesses and exhibits by August 30, 2024, as required under the Court's Scheduling Order. ECF No. 354. Thus, it appears that Smithers will be presenting no evidence at trial. The Government is submitting this Motion, however, in the event that Smithers does seek to introduce Dr. Murphy's testimony at trial and the Court permits Smithers to do so, despite his failure to notify the Government and the Court of his proposed witnesses.

I. BACKGROUND.

Following remand from the United States Court of Appeals for the Fourth Circuit based on *Ruan v. United States*, 597 U.S. 450 (2022), in which the Supreme Court of the United States clarified the applicable *mens rea* standard, *see United States v. Smithers*, 92 F.4th 237, 245, 252 (4th Cir. 2024), this Court scheduled a three-week jury trial beginning on December 2, 2024, as to the 859 counts charging Smithers with unlawfully distributing and dispensing Schedule II controlled substances, including two counts alleging that death resulted from the use of the controlled substances, all in violation of 21 U.S.C. § 841(a)(1), (b)(1)(C), and one count of maintaining a place for the purpose of unlawful distribution, in violation of 21 U.S.C. § 856. ECF Nos. 80, 337. On August 12, 2024, Smithers notified the Government of his intent to elicit expert testimony from Dr. Murphy. ECF No. 405. Smithers provided the Government with Dr. Murphy's "Expert Witness Report" that same day. *See* Ex. 1.

II. LEGAL STANDARD.

The party offering a proposed expert's testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). Federal Rule of Evidence 702, which governs the admissibility of expert testimony, provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

The Supreme Court elucidated that the district court must determine "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." *Daubert*, 509 U.S. at 592. "The first prong . . . necessitates an examination of whether the reasoning or methodology underlying the expert's proffered opinion is reliable—that is, whether it is supported by adequate validation to render it trustworthy. The second prong . . . requires an analysis of whether the opinion is relevant to the facts at issue." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260 (4th Cir. 1999) (citations omitted).

The district court should consider several factors when assessing the validity of a proposed expert's testimony, including:

> [(1)] whether the reasoning or methodology underlying the expert's opinion has been or could be tested;
>
> [(2)] whether the reasoning or methodology has been subject to peer review and publication;
>
> [(3)] the known or potential rate of error; and
>
> [(4)] the level of acceptance of the reasoning or methodology by the relevant professional community.

EEOC v. Freeman, 778 F.3d 463, 466 & n.4 (4th Cir. 2015) (quoting *Westberry*, 178 F.3d at 261 n.1). While "Rule 702 was intended to liberalize the introduction of relevant expert

evidence," the district court, as gatekeeper, should exclude "proffered evidence that has a greater potential to mislead than to enlighten." *Westberry*, 178 F.3d at 261.

The Fourth Circuit has affirmed a district court's exclusion of expert testimony when the expert's "unconventional" opinion "amounted to a wholly conclusory finding based upon his subjective beliefs rather than any valid scientific method" and contradicted the position of the applicable governmental regulatory agency and a majority of the expert's colleagues. *See Cooper*, 259 F.3d at 200–01; *see also Freeman*, 778 F.3d at 466–68 (affirming the district court's exclusion of expert testimony as unreliable where the expert only examined a subset of the data and "did not seek to utilize a sample size from the relevant time period, but purported to analyze all background checks with verified outcomes" and the court "identified an alarming number of errors and analytical fallacies in [the expert's] reports, making it impossible to rely on any of his conclusions"); *Hall v. Norton Co.*, No. 97-2770, 1998 WL 904829, at *2 (4th Cir. Dec. 29, 1998) (per curiam) (table) ("A court may refuse to allow an expert to testify if his factual assumptions are not supported by the evidence."). Other courts have concluded similarly. *See, e.g.*, *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1187 (S.D. Fla. 2022) ("When the gap is too great—when the leap is too far—a court may exclude an expert's opinion. Thus, if an expert makes an analytical leap from available data that no other scientist outside of the litigation has made, a court may consider that fact." (citations omitted)).

III. DISCUSSION.

The Government does not take issue with Dr. Murphy's credentials nor his specialized knowledge and training as a physician. However, Dr. Murphy's blanket conclusion that all the prescriptions charged in the Second Superseding Indictment (the "Indictment") were issued by Smithers legitimately, in the usual course of professional practice, and in an authorized manner is based on incomplete, outdated, and distorted research as well as his subjective beliefs that the "disproportionate narrative pertaining to the involvement and overall influence of opioid prescribing" has resulted in the "marshalling [of] an army of agents to go after physicians who are simply trying to alleviate the suffering of their patients . . . ." Ex. 1 at 4, 35, 38, 109. Dr. Murphy further opines on issues outside of his expertise, including as to Smithers' state of mind and conclusions of law. Accordingly, this Court should exclude Dr. Murphy's testimony in its entirety. In the alternative, the Government requests that the Court limit Dr. Murphy's testimony to only the issues and the charges to which the Court determines Dr. Murphy is qualified to opine.

1. Dr. Murphy's testimony should be excluded in its entirety.

In his report, Dr. Murphy purports to "have reviewed the records of the care provided to the patients named in the Indictment" and concludes "that the prescriptions for opioid pain medications were based on reasonable clinical judgment, were medically necessary and issued by Dr. Smithers for a legitimate medical purpose in each case." *Id.* at 7. However, Dr. Murphy elsewhere admits that he did not review the records of nine patients that are identified in the Indictment. *See id.* at 4. Moreover, Dr. Murphy contends

that he has relied on "the gold standard of reviews of clinical studies", *id.* at 23; yet, his research is outdated and his application of such skewed.

For these reasons, Dr. Murphy's testimony should be excluded as it is not based on sufficient data or facts; is not the product of reliable principles and methods; and does not reflect a reliable application of the principles and methods to the facts of this case.

A. Dr. Murphy relies on insufficient data and facts.

Smithers was provided the patient records associated with all 50 individuals identified in the Indictment through discovery. Dr. Murphy indicated in his report though that no records were provided to him for nine of the patients at issue, totaling over 200 of the 860 counts charged in the Indictment. *See id.* at 4. Dr. Murphy concludes that despite not reviewing these nine patient files, "it is reasonable to assume that additional documentation would likely be of similar quality and scope as that to which I currently have access." *Id.* at 45. Dr. Murphy further reasons that Smithers was not required to do a physical examination of each patient because "the observation-based physical examination data from Dr. Smithers' face-to-face in-person encounters was sufficient to allow him to make reasonable decisions regarding the management of his chronic pain legacy patients, especially considering the wealth of other data . . . Dr. Smithers documented in the records." *Id.* at 10–11 (emphasis omitted).

However, Dr. Murphy's factual assumptions that Smithers maintained "comprehensive, efficient, and sufficient" documentation" based on "observation-based physical examination[s]" of all his patients are belied by the actual evidence. *Id.* at 11, 30 (emphasis omitted); *see also id.* at 11 ("Dr. Smithers was the regular provider repeatedly

seeing his patients, thus he was always able to perform the 'observation' portion of a physical exam with each patient at each encounter." (emphasis omitted)). Most notably, Dr. Murphy did not review the records of DR. *See id.* at 4. As this Court knows from the first trial, DR had never seen Smithers as a patient, had never visited Smithers' clinic, and had neither requested nor received the prescriptions Smithers had issued in her name. ECF No. 358 at 435–49. Yet, without reviewing any records for DR—which included none of the forms Dr. Murphy lists as "appear[ing] regularly in the charts of patients noted in the Indictment," *see* Ex. 1 at 9—Dr. Murphy concluded, as to all counts alleged in the Indictment, including those concerning DR, that the prescriptions issued "for opioid pain medications were based on reasonable clinical judgment, were medically necessary and issued by Dr. Smithers for a legitimate medical purpose in each case." *Id.* at 7.

As to the patients whose records he did review, Dr. Murphy fails to cite or reference any of the specific documentation or records on which he relied for a majority of his conclusions. For example, while Dr. Murphy claims to have reviewed records for SM, he provides no explanation of what records he relied upon when he determined that each of the prescriptions were legitimately issued to SM. *See id.* at 99. He also fails to opine on how Smithers' issuance of an oxycodone prescription to SM in exchange for $300 in a Starbucks parking lot in Greensboro, North Carolina—where Smithers performed no kind of examination of SM—falls within the usual course of practice. ECF No. 358 at 458.

Dr. Murphy's proposed testimony is not based on sufficient facts or data, rendering his opinion unreliable.

B. Dr. Murphy's testimony is not the product of a reliable methodology, and his opinion is not based on a reliable application of that methodology to the facts.

Dr. Murphy relies on outdated research, methods, and principles to reach his wholesale conclusion that Smithers acted within the bounds of the law. He further distorts the research upon which he does rely, and he outright rejects any methodology that contradicts his opinions, without providing any basis in so doing. "As the Supreme Court has repeatedly held, 'nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.'" *See Cooper*, 259 F.3d at 203 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999)).

Dr. Murphy opines that "opioids are effective pain relievers," relying on the 2010 Cochrane Review and the Second Edition of the Massachusetts General Hospital Handbook of Pain Management, released in 2001. *See* Ex. 1 at 23–24. Citing the 2010 Cochrane Review, and apparently quoting from it, Dr. Murphy reiterates "that patients who are able to continue opioids long-term experience clinically significant pain relief." *Id.* at 23. In truth, the authors of that report concluded that "*weak evidence suggests* that patients who are able to continue opioids long-term experience clinically significant pain relief." Meredith Noble et al., *Long-Term Opioid Management for Chronic Noncancer Pain*, Cochrane Database (2010), *available at* https://pubmed.ncbi.nlm.nih.gov/20091598/ (emphasis added). That report further provides that "[m]any patients discontinue long-term opioid therapy (especially oral opioids) due to adverse events or insufficient pain relief." *Id.* Dr. Murphy conveniently alters the authors' findings—which were based on

searches of 10 databases up to May 2009, and thus, six years before the charged conduct at issue, *see id.*—to support his own conclusions.

Dr. Murphy's reliance on the over 20-year-old version of the Massachusetts General Hospital Handbook of Pain Management is also misleading. He quotes the handbook for the proposition that opioids "are the only pain medications that have no ceiling effect, and are therefore the only systemic treatment for severe accelerating pain," asserting that this finding "is as true now as it was then." Ex. 1 at 24 (emphasis omitted). The handbook, however, has since been updated twice, and the most recent 2021 edition does not contain the language quoted by Dr. Murphy. *See* Ex. 2. Instead, the updated handbook provides that "[o]pioid prescriptions for acute and chronic pain and the risk of addiction potential are currently undergoing a paradigm shift. Data are currently inconclusive for the efficacy of opioids for the treatment of chronic pain." *Id.* at 166–67. The updated handbook further relies on the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, which recommends for noncancerous, chronic pain that physicians "should prescribe the lowest effective dosage . . . [w]hen opioids are started," further detailing the caution physicians should exercise in increasing dosage. *See id.* at 167–68.

Dr. Murphy also repeatedly cites the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain for the proposition that "risk mitigation strategies are unproven," in which he downplays the usefulness of urine screens. *See* Ex. 1 at 29. But in fact, the 2016 CDC Guideline recommended clinicians to "use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs." Deborah Dowell et al., *CDC*

Guideline for Prescribing Opioids for Chronic Pain, CDC Morbidity and Mortality Weekly Report (Mar. 18, 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm. Yet again Dr. Murphy cherry picks language to support his theories of the relevant data, rather than reliably applying accepted methodology.

On the other end of the spectrum, Dr. Murphy relies on principles promulgated in response to the COVID-19 pandemic, which occurred more than two years after the conduct charged in the Indictment. *See, e.g.*, Ex. 1 at 11, 30, 114 (citing "How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency"). The policies relied upon, which were promulgated by the Drug Enforcement Administration, went into effect March 31, 2020, and only remained in effect until—at the latest—the end of the public health emergency, or May 11, 2023. *See* How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency, *available at* https://www.deadiversion.usdoj.gov/GDP/RESCINDED_(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf. Any opinion based on such methodology—or application of such to the facts of this case which occurred well before the COVID-19 pandemic—is unreliable.

Dr. Murphy fails to include or rely upon any updated guidance as to the efficacy of long-term use of opioids in the report at issue. Instead, Dr. Murphy pointedly ignores updated methodology that contradicts his opinions. *See, e.g.*, Ex. 1 at 24 ("Recently, conclusions about the lack of opioid efficacy have been drawn from seriously flawed studies characterized by inadequate experimental designs."); *see also id.* at 25

("Policymakers, pharmacy benefit managers, regulators, and a number of ill-informed medical professionals have wrongly embraced the concept of morphine milligram equivalent (MME) to attribute escalating risks based on overall daily opioid dose.").

Perhaps most concerning, Dr. Murphy has been made aware of the deficiencies in his methodology, which he has repeatedly utilized, by both the Government and other courts in previous trials. *See United States v. Adrian Dexter Talbot*, Case No. 2:21-CR-111 (E.D. La. July 19, 2024) ("Ex. 3"), at 2168:12–2170:5 (discussing the omitted language from the quoted Cochrane article, and how he had previously been informed of the omission in a prior trial); *id.* at 2164:4–2168:5 (discussing the updated language from the 2021 edition of the Massachusetts General Hospital Handbook of Pain Management, and how he had been presented with this edition at a prior trial); *see also United States v. La*, No. 3:22-cr-00163, 2022 WL 2707884, at *1 (M.D. Tenn. July 12, 2022) (excluding any testimony regarding "changes in medical standards that were made to reflect emergency conditions during the coronavirus pandemic"). Despite being repeatedly examined on more recent studies, including the 2021 edition of the Massachusetts General Hospital Handbook of Pain Management, Dr. Murphy testified just two months ago in July 2024 that he was not "aware of any guidance that has come out since 2016, that has suggested that pain medications are not effective for long-term pain." Ex. 3 at 2207:12–16.

Dr. Murphy's overall reliance on outdated and otherwise skewed opioid research is akin to an expert today relying on purported medical authority from the 1930s that smoking cigarettes poses no health risks. "The sheer number of mistakes and omissions in [Dr. Murphy's] analysis renders it 'outside the range where experts might reasonably differ.'"

Freeman, 778 F.3d at 467 (quoting *Kumho Tire*, 526 U.S. at 153). Accordingly, Dr. Murphy's proposed testimony is unreliable, and it should be excluded in its entirety at trial.

2. In the alternative, Dr. Murphy's testimony should be limited.

If the Court permits Dr. Murphy to testify at trial, the Court should prohibit Dr. Murphy from testifying as to the opinions set forth below, which are inadmissible under the Federal Rules of Evidence and the caselaw promulgated thereunder.

A. Dr. Murphy should be prohibited from providing an opinion as to the charges relating to the nine patients whose records he did not review.

Dr. Murphy failed to review any records for the following nine patients identified in the Indictment, which relate to the corresponding counts enumerated below:

1. RB, counts 3–20
2. FB, counts 21–55
3. DD, counts 165–193
4. JMay, counts 535–577
5. ChM, counts 586–604
6. JMo, counts 628–660
7. DR, counts 717–724
8. ST, counts 740–759
9. TW, counts 762–783

See Ex. 1 at 4; ECF No. 80. As explained above, any conclusion by Dr. Murphy as to whether Smithers issued these prescriptions for a legitimate medical purpose and within the usual course of practice would be based on insufficient data and facts. Accordingly,

Dr. Murphy should not be permitted to offer any opinion as to any of the charged prescriptions relating to the nine individuals whose records he did not review.

B. Dr. Murphy should be prohibited from testifying on the applicable law.

Throughout his report, Dr. Murphy opines on legal matters that are beyond his expertise and the confines of admissible expert testimony. The Government recognizes that Dr. Murphy may testify—if permitted to testify at trial—as to whether, in his opinion, a prescription was issued for a legitimate medical purpose, in an authorized manner, and within the bounds of the usual course of professional practice. *See United States v. Boccone*, 556 F. App'x 215, 226 (4th Cir. 2014) (quoting *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)). However, the following opinions by Dr. Murphy should be excluded as impermissible legal conclusions. *See McIver*, 470 F.3d at 562 ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *cf. La*, 2022 WL 2707884, at *1 (barring Dr. Murphy from testifying as to legal conclusions, including the "legal definition of the 'usual course of practice'").

First, in his report, Dr. Murphy purports to provide "an understanding of the legal standards applicable to the authorization to prescribe controlled substances," under the sections entitled "Legitimate Medical Purpose in the Usual Course of Professional Practice," "Usual Course of Professional Practice," and "Clinical Guidelines Are Not the Standard of Care." Ex. 1 at 5–7, 20–22. In so doing, Dr. Murphy relies on his own interpretations of the Federal Register and 21 C.F.R. § 1306.4, to provide legal definitions of the "usual course of professional practice." *Id.* He further defines the "standard of care,"

and provides that failing to meet it does not equate to a violation of the law. *Id.* Such interpretations are matters "better handled by the judge," and should be excluded. *See United States v. Offill*, 666 F.3d 168, 175 (4th Cir. 2011).

Second, and similarly, Dr. Murphy should be prohibited from testifying as to any "legal disputes" regarding "whether [21 C.F.R. § 1306.4] defines the scope of a doctor's prescribing authority" as to violations of 21 U.S.C. § 841. *See* Ex. 1 at 5.

Finally, Dr. Murphy appears to opine that when laws conflict with his interpretation of accepted professional medical standards, doctors should conform with the latter and disregard the former. *See id.* at 23 ("Professional standards in healthcare are conceived by healthcare providers, while laws are created by lawmakers. Therefore laws can support professional standards in medicine, but they do not define professional standards."). Dr. Murphy should not be permitted to offer any testimony opining that Smithers was not required to follow the law, or that any deviation from the law was ethically permissible.

C. Dr. Murphy should be prohibited from opining on Smithers' state of mind.

In a criminal matter, pursuant to Federal Rule of Evidence 704(b), "an expert witness must not state an opinion about whether the defendant did or did not have a mental state or condition that constitutes an element of the crime charged or of a defense. Those are for the trier of fact alone." Accordingly, Dr. Murphy should be prohibited from testifying as to the following opinions, quoted from his report, on Smithers' alleged mental state. *See United States v. Perkins*, 470 F.3d 150, 158 (4th Cir. 2006); *United States v. Crow*, 603 F. App'x 197, 199 (4th Cir. 2015); *cf. La*, 2022 WL 2707884, at *1 (prohibiting Dr. Murphy from testifying as to the defendant's state of mind).

- "The records I reviewed indicate that Dr. Smithers was, indeed, a single committed physician taking primary responsibility for the management of his patients' therapy, and in particular, the prescribing of opioid medications to treat his patients' chronic pain in an effort to alleviate their suffering." Ex. 1 at 6.

- "[Dr. Smithers'] acted in an effort to improve his patients' quality of life and alleviate their suffering." *Id.* at 8.

- "Dr. Smithers chose analgesics properly in an effort to achieve an optimal balance between maximum analgesia and minimum adverse effects." *Id.* at 13.

- "Dr. Smithers was clearly trying to be observant of aberrant drug-taking behavior, which might prompt him to suspect deeper problems with abuse or diversion of opioids." *Id.* at 14.

- "Dr. Smithers' clinical actions in all cases I reviewed were consistent with that of a physician whose aim is to alleviate the suffering of his patients he believes to have pain." *Id.* at 17.

- "Dr. Smithers' patients had pain, and the treatments he provided were for the legitimate medical purpose of alleviating their suffering." *Id.* at 18.

- "Dr. Smithers' primary aim was not to collect data on his patients to share with other entities, although other entities were indeed collecting data on Dr. Smithers himself. (e.g., PDMPs, pharmacies, drug companies, insurance companies paying for prescriptions). Dr. Smithers documented in the medical records to facilitate his care of his patients. He accomplished this goal." *Id.* at 30.

- "Dr. Smithers had ample information that was sufficient for him to determine that the prescriptions were for a bona fide medical purpose and that potential benefits to the patients outweighed the potential risks." *Id.* at 32.

- "[U]nderstanding the authentic root causes and historical facts with regards to how opioid prescribing ballooned in the latter part of the 20th century, continued early on, and later began to wane, allows critical insight into how and why well-intentioned doctors, like Dr. Smithers, came to rely upon this legitimate pharmacotherapeutic treatment to such a great extent in circumstances where they believed they were compassionately caring for patients suffering with chronic pain." *Id.* at 35.

- "Many primary care physicians, like Dr. Smithers, prescribe opioids to patients who, in their clinical judgment, need this level of care, praying that their

prescribing will not trigger a medical board audit, or worse, lead to a criminal investigation." *Id.* at 40.

- "[W]ith specific respect to the Indictment, as Dr. Smithers used his clinical judgment—based upon his understanding of the science, clinical evidence, training, experience, and intuition—and reasoned that it was in his patient's best interest to receive a prescription for opioid pain medication, it is misguided, harmful, and just plain wrong for anyone to jump to the conclusion that this course of treatment was illegitimate." *Id.* at 41.

Dr. Murphy lacks any personal knowledge of Smithers' state of mind at the time he issued the prescriptions charged in the Indictment. As such, and pursuant to Federal Rule of Evidence 704, any proposed testimony by Dr. Murphy as to Smithers' mental state should be excluded.

D. Dr. Murphy should be prohibited from testifying as to unsupported conclusory opinions, as well as opinions outside his areas of expertise.

Dr. Murphy offers several opinions throughout his report that are "rooted in 'subjective belief or unsupported speculation,'" which "does not suffice." *Zuckerman v. Wal-Mart Stores East, L.P.*, 611 F. App'x 138, 138 (4th Cir. 2015) (mem.) (quoting *Daubert*, 509 U.S. at 590). Moreover, Smithers appears to seek to qualify Dr. Murphy as an expert in anesthesiology, pain medicine, preventive medicine, and addiction medicine, *see* ECF No. 405; while Dr. Murphy may be qualified as an expert in these fields, "[t]he fact that a proposed witness is an expert in one area, does not *ipso facto* qualify him to testify as an expert in all related areas." *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 391 (D. Md. 2001) (collecting cases).

In all, the following proposed opinions, quoted and cited from Dr. Murphy's report, are irrelevant and unreliable and would only serve to confuse the issues and the jury, and

they should be excluded at trial.

- Any conclusion that Dr. Smithers acted morally or compassionately, or engaged in actions required by moral and compassionate practitioners, which confuses the issues as to whether Smithers violated the law. *See, e.g.*, Ex. 1 at 7 ("Dr. Smithers' patients in the Indictment were suffering, and the care that Dr. Smithers provided his patients was authorized, reasonable, and aimed at treating their pain and alleviating their suffering. In sum, Dr. Smithers was practicing medicine morally, ethically, and in the usual course of professional practice."); *see also id.* ("Compassionate health care providers, like Dr. Smithers, must fulfill their moral imperative to treat pain, recognizing the need to minimize risks associated with the various medications available to treat pain . . . .").

- Any opinion relating to or deriving from the entire section entitled "The Chronic Pain Experience," *see id.* at 18–20, in which Dr. Murphy speculates as to the general barriers and burdens that all pain management physicians and patients face, drawing conclusions as to Dr. Smithers and his patients specifically without any evidentiary support. *See, e.g., id.* at 20 (discussing the limitations of providing and seeking pain management care in "rural Virginia," even though many of Smithers' patients traveled from outside the Commonwealth of Virginia, sometimes for hours at a time).

- Any conclusion about the impropriety of various standards and laws to regulate opioid use and abuse. *See, e.g., id.* at 22 ("Despite warnings to the contrary, the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain has been misrepresented and misapplied by numerous states, federal agencies, pharmacies, pharmacy benefit managers, payers, and supposed experts. Based on misapplication of the CDC Guideline, regulations and restrictions on opioid prescribing and dispensing have resulted in rigid limitations in many areas of policy, practice, and regulation."); *see also id.* at 25 ("Policymakers, pharmacy benefit managers, regulators, and a number of ill-informed medical professionals have wrongly embraced the concept of morphine milligram equivalent (MME) to attribute escalating risks based on overall daily opioid dose. . . . Therefore, MME should not be used to assess risk, including overdose risk, in any meaningful statistical way."); *id.* at 29 ("At any rate, when caring for patients with chronic pain, especially if the patient is physically dependent on medication, it is *inescapably true* that some patients who have inconsistent drug screens will still need pain relief and continued medication. It is certainly within the standard of care for a physician, like Dr. Smithers, to evaluate his/her patient and decide whether it is appropriate to continue opioids under these circumstances. There are no *legitimate* guidelines that require de-prescribing an opioid medication in this situation—not nationally and not in the state of Virginia." (emphasis added)).

- Any unsupported, blanket conclusory statements. *See, e.g.*, *id.* at 27 ("Dr. Smithers' patients named in the Indictment were tolerant to their opioid medication."); *see also id.* ("Dr. Smithers' patients were physically dependent on their opioid medication."); *id.* at 29 ("The fact remains that there is no reliable way to determine whether any one patient will be or is abusing or diverting drugs, and refusal to provide effective pain medications to patients due to a fear that a few patients may be abusing would result in too many patients needlessly suffering pain.").

- Any opinion based on principles promulgated as a result of the COVID-19 pandemic. *See, e.g.*, *id.* at 11, 30 (citing "How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency").

- Any assessment and application of laws and regulations from a non-federal, out-of-state sovereign. *See, e.g.*, *id.* at 31 (describing Kentucky's regulations for prescribing opioids).

- Any opinion relating to or deriving from the entire section entitled "In Comparison to His Peers, Dr. Smithers' Prescribing Was in the Norm," *see id.* 32–35, in which Dr. Murphy relies on data before and after the timeline set forth in the Indictment and summarily speculates that "[i]n a rural Virginia community, like Martinsville, abrupt closure of a pain clinic like Dr. Smithers' clinic, can be expected to force a flood of suffering patients to the streets and back alleys to gain access to pain medications—at their own peril—creating a public health crisis that might have been avoided had concerns about Dr. Smithers' practice been brought before a more medically-informed regulatory body such as the Virginia Board of Medicine as opposed [to] a federal criminal courtroom of the U.S. Department of Justice." (emphasis omitted).[2]

- Any opinion relating to or deriving from the entire section entitled "The Opioid Crisis," *see id.* at 35–40, in which Dr. Murphy alleges to distill and portray "the authentic root causes and historical facts" underlying "the overdose crisis" that has led to "a backlash against prescription opioids" and the "marshalling [of] an army of agents to go after physicians who are simply trying to alleviate the suffering of their patients . . . [which] has had a chilling effect on physicians' ability to treat their suffering patients with effective therapeutic regimens."

- Any opinion relating to or deriving from the entire section entitled "A Public

[2] Dr. Murphy further conflates the decline in the dispensing rate of opioids in Virginia (from 2019 to 2021) against the increase in overdose deaths (from 2018 to 2021), as the former is based on a rate of 100 persons while the latter is based on a rate of 100,000 persons. *See id.* at 33–34.

Health Approach Is Needed," *see id.* at 40–41, in which Dr. Murphy opines on the propriety of criminal enforcement against physicians, indicating that "the focus cannot continue to be on hammering well-meaning doctors, even when they make prescribing judgments that, to some, may seem excessive (i.e., there are other venues outside of a criminal courtroom that are better suited to address these circumstances, such as medical boards, peer review agencies, special societies, and credentialing bodies)," and summarily concludes that "it is misguided, harmful, and just plain wrong for anyone to jump to the conclusion that [Smithers'] course of treatment was illegitimate."

- Any opinion relating to or deriving from the entire section entitled "Virginia Blames Big Pharma," *see id.* at 41–45, in which Dr. Murphy confuses the issues by referencing a civil complaint filed by the Commonwealth of Virginia against Purdue Pharma, and provides that Smithers cannot be blamed for the opioid crisis and "should not be held criminally liable for clinical decision-making that was consistent with a multitude of his Virginia physician peers—even if they had all been duped by Big Pharma and their paid army of drug reps, Key Opinion Leaders, and complicit host of financially supported professional societies." (emphasis omitted).

- Any opinion as to the cause of death of HH. *See id.* at 87 ("Opinion—suicide vs. accidental overdose.").

IV. CONCLUSION.

Dr. Murphy's opinions, as evinced in his report, are unsupported by the evidence in this case, much of which he candidly admits he failed to fully review. Moreover, the scientific data and methodology upon which he bases his opinions is outdated or distorted, and Dr. Murphy patently disregards renewed studies and practices that conflict with his methodology and reasoning. Finally, Dr. Murphy repeatedly offers opinions that are irrelevant, confusing, and outside the scope of this trial and his expertise. As the party proposing to admit Dr. Murphy's testimony, Smithers has failed his burden of establishing that Dr. Murphy's testimony is admissible.

For all these reasons, this Court should exclude, or in the alternative limit, Dr.

Murphy's proposed testimony at trial.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 13, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send a copy to the counsel of record.

s/ Corey Hall
Assistant United States Attorney